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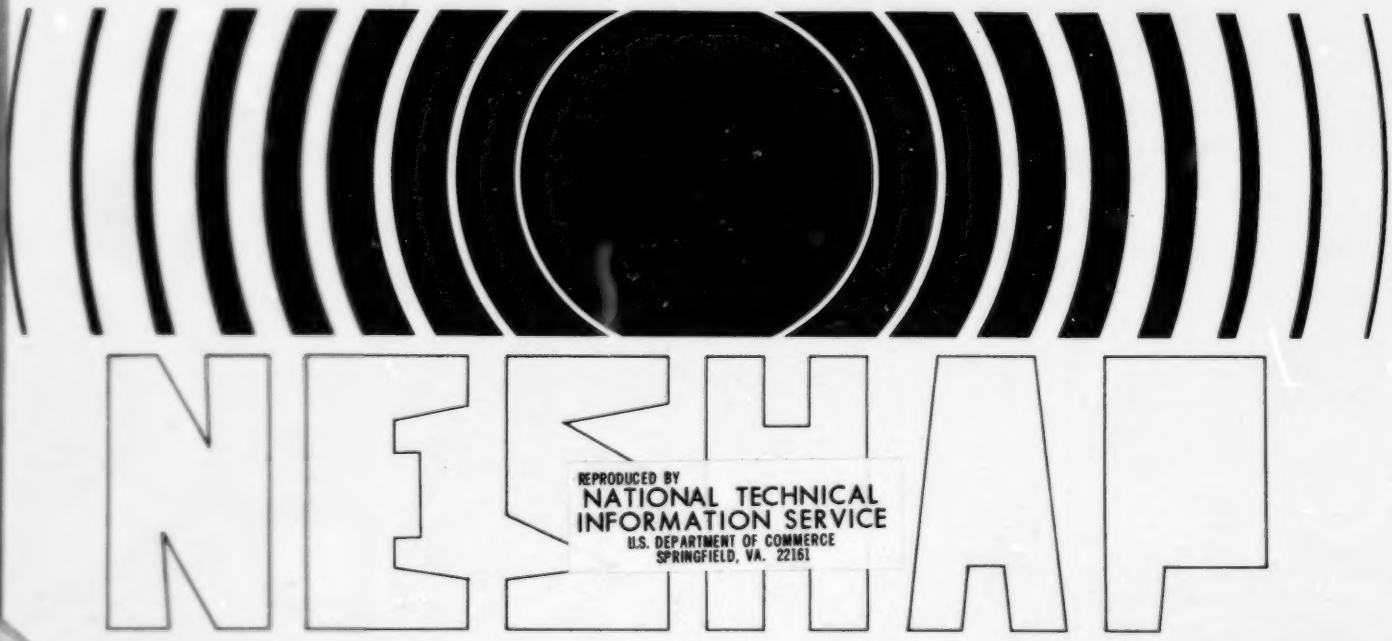
Response to Comments for Final Rules

Volume II



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16. ABSTRACT

In December 1983, the Administrator of the EPA formed a Science Advisory Board Subcommittee to review the methodology used by the Office of Radiation Programs in assessing health risks from airborne release of radionuclides. In addition, new technical data was gathered which included the results of radionuclide emission tesing at calciners at three elemental phosphorus plants. New information also became available on the cost and effectiveness of methods for reducing radon emissions from underground uranium mines. Because the Agency intended to consider this new information in the ongoing rulemaking, public comment was requested on the new information, (49 FR 33695, August 24, 1984).

This document summarizes public comments on the new information and EPA's response to them. In addition, Section 2 of the document contains EPA's response to the Science Advisory Board Subcommittee's comments.

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RESPONSE TO COMMENTS

FINAL RULES FOR RADIONUCLIDES

VOLUME II

October 22, 1984

Office of Radiation Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

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1.0 INTRODUCTION

On April 6, 1983, EPA published in the Federal Register (48 FR 15076) proposed standards for certain categories of radionuclides. Volume I of the Response to Comments (EPA 521/1-84-023-1) summarizes major concerns and issues arising from written and oral comments on the April 6 proposal, as well as EPA's response to these.

In December 1983, the Administrator of the EPA formed a Science Advisory Board Subcommittee to review the methodology used by the Office of Radiation Programs in assessing health risks from airborne release of radionuclides. In addition, new technical data was gathered which included the results of radionuclide emission testing at calciners at three elemental phosphorus plants. New information also became available on the cost and effectiveness of methods for reducing radon emissions from underground uranium mines. Because the Agency intended to consider this new information in the ongoing rulemaking, public comment was requested on the new information, (49 FR 33695, August 24, 1984).

This document summarizes public comments on the new information and EPA's response to them. In addition, Section 2 of the document contains EPA's response to the Science Advisory Board Subcommittee's comments.

2.0 EPA's REPONSE TO THE SCIENCE ADVISORY BOARD SUBCOMMITTEE COMMENTS ON RISK ASSESSMENT

In response to criticism that the Agency did not have sufficient outside review of its methods used to assess risks due to radionuclides, the Administrator formed a subcommittee of the Agency's Science Advisory Board (SAB) to review the scientific basis of the proposed standards for radionuclides. The Subcommittee held three public meetings: the first on January 16, 1984, the second on February 21-22, 1984, and the third on March 22, 1984. At these meetings, the Subcommittee was briefed by Agency staff on the methods used in estimating risks caused by airborne radionuclides. The panel heard from members of the public on the Agency's risk assessments as well. The Subcommittee also held executive sessions to consider the information presented by the Agency and the public.

Transcripts of the public meetings are available in the Docket. The Subcommittee's final report, entitled "Report on the Scientific Basis of EPA's Proposed National Emissions Standards for Hazardous Air Pollutants for Radionuclides," was transmitted to the Administrator on August 17, 1984. A copy of this report is available in the Docket.

In the Executive Summary of its report, the Subcommittee noted that its activities could be viewed as addressing two interrelated questions. First, did the Agency's staff collect the scientifically relevant data and use scientifically defensible approaches in modeling the transport of radionuclides through the environment from airborne releases, in calculating the doses received by persons inhaling or ingesting this radioactivity, and in estimating the potential cancer and genetic risks of the calculated doses? Second, are the individual facts, calculational operations, scientific judgments, and estimates of uncertainty documented and integrated in a clear and logical manner to provide a risk assessment that can be used as a scientific basis for risk management purposes, i.e., standard-setting? With regard to the first question, the Subcommittee concluded that EPA had gathered the appropriate scientific information needed for a risk assessment in a technically proficient manner.

The Subcommittee's greatest criticism in its report was related to the second question. They concluded that EPA had not assembled and integrated the available scientific data in the format of a risk assessment that provides a scientifically adequate basis for regulatory decisions on airborne radionuclides. The panel suggested that an intermediate step was necessary between the collection of the relevant technical information and the selection of regulatory options. Specifically, they encouraged the Agency to assemble an integrated risk assessment document that would lead a decisionmaker step-by-step from the identification of emission sources, through the calculation of radiation doses and health risks and the associated degree of uncertainty. They

believe that such an assessment would enable the decisionmakers to better evaluate the variety of regulatory options available. Only in this way, did the Subcommittee feel that a policymaker could be presented with all the facts necessary to make a responsible regulatory decision. Further, this analysis would enable the scientific community and the public to understand the rationale and basis for the Agency's actions.

The Subcommittee made several technical suggestions on how EPA could improve its assumptions, models, and methods for estimating risks. Most of the technical suggestions have been incorporated into EPA's risk assessment procedures. The risk assessment for the final rule reflects all of these modifications. Responses to each of the technical comments are presented later in this report. Some of these technical suggestions involve additional research to improve future risk assessment methods. These suggestions will be used as EPA conducts new studies.

The Agency recognizes and is concerned about the adverse criticism of its processes by its own Science Advisory Board. The Agency does believe that, on balance, its risk estimates for specific sources of radionuclide emissions are accurate within the limitations inherent in making such estimates. However, it acknowledges that the criticism of the Board does cloud the rulemaking record, and that the Subcommittee's concerns, by their very nature, cannot be fully addressed within the time available for this decision. Nevertheless, the final Background Information Document has been greatly modified to encompass the format and suggestions of the Subcommittee to the extent possible. The Subcommittee has not yet had an opportunity to review this revised document.

The Subcommittee made six procedural suggestions for improving the Agency's risk assessment methods. These recommendations will be incorporated into the Agency's procedures and processes. Responses to these six recommendations are presented in Section 2.1 of this report.

The Subcommittee also made six recommendations for areas in which additional research would be helpful. The Agency appreciates receiving these recommendations and will work with the radiation research community to try to promote additional studies in these areas.

2.1 Responses to the Procedural Recommendations

Recommendation Number 1: ...that procedures be established to delineate more clearly the risk assessment and risk management aspects of the total radiation standards development process.

Response: The Subcommittee was not particularly clear as to the specific problem this recommendation was addressing, and how the Agency could best accommodate their concerns. However, during their deliberations it appeared that several of the Subcommittee's members had

difficulty distinguishing and separating risk assessment and risk management issues. To accommodate this recommendation, EPA will adopt procedures to more clearly delineate risk assessment and risk management. They will include determining the appropriate time to schedule reviews by SAB and the scientific community, determining the nature of the materials to be submitted for scientific review, and determining the role of the scientific review in the risk management process.

Recommendation Number 2: ...that for each regulatory action considered, the risk assessment process includes development of a risk assessment document which makes reference, as appropriate, to more detailed analyses found in the scientific literature.

Response: The Agency will include a risk assessment document for each of its regulatory actions involving radiation. The Subcommittee suggested that such a document include the conceptual framework for assessing radiation risks, starting with identifying sources of radionuclide emissions, analyzing the movement of radionuclides from a source through environmental pathways, calculating doses received by individuals and populations, estimating genetic and somatic health effects, and presenting a statement of uncertainty in the risk estimates. They indicated that uncertainty should be expressed as with lower and upper bounds around central estimates for cancer and genetic end points.

The Agency will prepare its risk assessment documents for radiation along the general framework recommended by the Subcommittee. However, it is important to note that, at least for radiation risk assessments performed in the near future, the ability to evaluate uncertainties is limited. Each element of the risk assessment has uncertainties. Consequently, to develop an overall estimate of the uncertainty, it is necessary to have techniques which can propagate uncertainties throughout the assessment. The development of such techniques is currently in the research stage. Well established models and techniques are not available. EPA and other groups are working to improve analytical capabilities in uncertainty analysis, but it will be several years before satisfactory methods are available. In the meantime, EPA will provide a qualitative evaluation of uncertainties in the various elements of the risk assessment. This will include determining which elements have the greatest uncertainty and which uncertainties have the greatest impact on the risk estimates. The Agency will provide quantitative estimates of uncertainty to the extent feasible, but it must be recognized that such estimates are likely to be based primarily on scientific judgment rather than rigorous mathematical analysis.

Recommendation Number 3: ...that such a risk assessment document be prepared for airborne radioactivity as a basis for making any further risk management decisions on the airborne radionuclides emission standards, including promulgation of final standards.

Response: The Agency has prepared an integrated risk assessment document for the final radionuclide rule following the framework suggested by the Subcommittee.

This integrated risk assessment is the final Background Information Document. It is organized into two volumes. The first volume contains background information on radiation protection and a detailed description of the Agency's procedures and methods for estimating radiation dose and risk due to radionuclide emissions to the air. Volume II contains detailed risk estimates for each source of emissions, which were performed according to the procedures given in Volume I. Each chapter contains a general description of the source category, a brief description of the processes leading to emissions of radionuclides to the air, a summary of emissions data, and estimates of radiation doses and health risks to both nearby individuals and larger populations.

The Agency has had only about two months between officially receiving the Subcommittee's report and the deadline established by the court for final action. Completion of this integrated risk assessment in such a short period has been a monumental task . It would have been desirable to have had more time to refine the risk assessment. Nonetheless, the Agency believes that the risk assessment performed for the final rule reflects the state-of-the-art in assembling, analyzing, evaluating, and presenting the relevant scientific information.

Recommendation Number 4 ...that a standing committee be created as a part of the EPA Science Advisory Board to review risk assessments for radiation standards and to provide advice on the full range of scientific activities of the Office of Radiation Programs.

Response: EPA believes that a standing subcommittee would be useful and is in the process of establishing such a subcommittee. However, the charter will be broader than just reviewing the activities of the Office of Radiation Programs. It will review the scientific activities of all of the programs in EPA that deal with radiation.

Recommendation Number 5 ...that procedures be developed for soliciting and receiving public comment and SAB review on radiation risk assessments before proposed standards are developed.

Response: EPA agrees that it would be beneficial to have its scientific assessments reviewed prior to the development of standards. This would help remove risk management issues from the scientific review, and it would enable scientists to focus on the scientific issues in a well structured, unhurried manner. EPA will schedule the review of risk assessments in accordance with this recommendation, to the extent practical. Complying with this recommendation may add one year or more to the period needed to complete a rulemaking. Court ordered deadlines

and other constraints sometimes hinder the Agency's ability to conduct such extensive reviews prior to the development of proposed rules and other risk management decisions. The Agency is aware of the difficulties encountered when scientific reviews are conducted after standards have been proposed and will try to avoid such conflicts, if possible.

Recommendation Number 6 ...that steps be taken to enhance communication between the Office of Radiation Programs and other staff offices of the Agency and the scientific community on issues related to risk assessment.

Response: The Office of Radiation Programs was one of the first offices in EPA and the Federal Government to perform risk assessments methods. Many of the techniques used for radiation risk assessments have been adapted for use in estimating risks from toxic chemicals. Still, EPA agrees that technical exchange between all scientific groups performing risk assessments could be improved.

The Agency is taking several steps to foster better communication. A forum has been established at EPA to exchange information pertinent to risk assessments among the program offices. Guidelines are being developed to insure that scientific information is evaluated in a consistent manner. EPA has requested the National Academy of Sciences to undertake a new review of the effects on exposure to low levels of ionizing radiation. This review will consider the effects of high and low LET (linear energy transfer) radiation. Further, the Agency is planning to seek advice from the National Council on Radiation Protection (NCRP) on various scientific issues, including risk assessment for airborne emissions of radionuclides.

2.2 Response to Technical Comments and Recommendations

Comment 1: The Subcommittee raises several questions about the basic structure of the food chain section of AIRDOS-EPA. For example, the processes of resuspension, rain splash, absorption of surficial deposits into foliar tissues, and soil ingestion by beef and dairy cattle do not seem to be included in the code. (Page 17) Note: Page number refers to that in "Report on the Scientific Basis of EPA's Proposed National Emission Standards for Hazardous Air Pollutants for Radionuclides."

Response: The degree of detail required in a risk assessment model depends on the purposes for which the model is being used. In the case of radionuclide air emissions, the major impact on human health is due to the inhalation of airborne radioactivity. The AIRDOS-EPA ingestion model is clearly adequate to establish the relative importance of the food pathway, and to demonstrate that the food pathway is not particularly significant in estimating the total risk from emissions to air.

Consequently, the food pathway is not an important consideration in making regulatory decisions regarding radionuclide emissions. Moreover, many of the processes explicitly identified by the Subcommittee have not been neglected, e.g., resuspension, rain splash, and absorption. The values for the intercept fraction (that fraction of deposited activity which is intercepted by plant surfaces) used in the calculations are based on field measurements which include the effects of these processes. The measured values do not, however, allow the effects to be quantified separately. Soil ingestion by livestock is not included, as EPA is unaware of any concensus on values for this parameter. In view of the low significance of the food pathway, it is difficult to envision that this process would affect regulatory decisions concerning air emissions.

Comment 2: Furthermore, several basic human food types are not explicitly modeled, such as fish, cheese, poultry, eggs, and red meats other than beef. These omissions do not appear to be offset by higher human consumption rates of similar food directly modeled. (Page 17)

Response: These omissions were offset by adjusting consumption data for similar foods. For most radionuclides, good data on transfer coefficients to meats are available only for beef. Therefore, we have used the concentration in beef as a surrogate for that in other meat and then used a meat utilization factor which includes the consumption of poultry and other meats as well as beef. This "offset by higher human consumption rates of similar foods" is discussed in chapter six of the final BID. We agree that the model should be augmented to include specific transfer coefficients for additional foodstuffs as data become available, so that it will be more useful for situations where ingestion is a significant pathway. In the case of interest here, there would be a negligible change in the total risk if we had detailed data for all food stuffs, since the food pathway contributes only a small fraction of the total risk.

Comment 3: AIRDOS-EPA appears to be structured to average across seasons ... disregards the significant seasonal fluctuations ... A further limitation of this constant-parameter, steady-state model becomes clear if it is applied to radionuclide releases which are short-term, time-variant, or sporadic. (Pages 17-18)

Response: The air emissions of concern are chronic releases which are expected to be fairly uniform throughout the year. AIRDOS-EPA computes average intakes and exposures across seasons for the various pathways to man. If releases of radionuclides had a strong variation which was particularly significant to the assessment, AIRDOS-EPA would be modified. Limitations of the AIRDOS methodology are considered when performing and evaluating risk assessments so that it is not used inappropriately.

Comment 4: Subcommittee statement: "... it would seem more reasonable to adopt NRPB values," ... than "EPA values for gastrointestinal absorption of transuranic radionuclides." (Page 21)

Response: The Agency has included the cited lower NRPB values in the final BID. EPA believes inclusion of both the EPA and the NRPB values for gastrointestinal absorption is appropriate since both sets are now being considered by the ICRP in their ongoing revision of ICRP Publication 19, "The Metabolism of Compounds of Plutonium and Other Actinides." It should be noted, however, that the EPA Science Advisory Board's Subcommittee on High Level Waste recommended that the EPA values be used in the assessment of the risk from transuranic wastes.

The World Health Organization has adopted the NRPB estimates for gut absorption of transuranics (Environmental Health Criteria 25: Selected Radionuclides, WHO, Geneva, 1983; Nuclear Power: Health Implications of Transuranic Elements, European Series No. 11; WHO, Copenhagen, 1982). However, they noted that the estimate was based on animal studies and "Qualitative support for the plutonium numbers is provided by autopsy data from a group of reindeer-herding northern Finns, who ingest large quantities of plutonium-rich reindeer liver [M3]. Their plutonium burdens seem to be no higher than those of southern Finns, who do not ingest these relatively large quantities of plutonium. A difference should have been apparent if the fraction absorbed from the gastrointestinal tract had been much greater than 10^{-4}." (Environmental Health Criteria 25, 1983).

Reports from the Finnish investigators (H. Mussalo-Rauhamaa, Accumulation of Plutonium from Fallout in Southern Finns and Lapps, University of Helsinki, Finland, 1981; H. Mussalo-Rauhamaa, et al., Plutonium in Finnish Lapps - An Estimate of the Gastrointestinal Absorption of Plutonium by Man Based on a Comparison of the Plutonium Content of Lapps and Southern Finns, Health Physics 46:549-559, 1984) show that such a difference was observed. Further, they estimate the gastrointestinal absorption of soluble plutonium in man to be 8×10^{-4} to 9×10^{-4}. If they are correct, the EPA would not underestimate absorption but the NRPB would.

There are no comparable data for other transuranics, but studies in swine, selected because "the primary strengths of swine as the animal model are their remarkable anatomic and physiologic likeness to man with respect to the cardiovascular system, digestive tract, skin, nutritional needs, bone development and mineral metabolism," have provided new data on americium (G.R. Eisele, et al., Americium Absorption from the Gastrointestinal Tract of the Pig, NVO-252, Oak Ridge Associated Universities, Oak Ridge, Tennessee, 1982). They found net absorption of ^{241}Am from the gastrointestinal tract of swine varied from 0.7×10^{-3} to 1.6×10^{-3} and the absorption was estimated at 1.1×10^{-3}, similar to the EPA estimated absorption in man.

Differences between NRPB values and those used by EPA in preparing the draft BID are appreciable only for plutonium oxides. Unlike the NRPB, EPA takes account of the fact that the solubility of plutonium oxides varies, depending on the temperature at which they are formed, and that, even in the oxide form, high specific activity plutonium isotopes have greater solubility than plutonium-239. Therefore, the NRPB estimates may underestimate absorption. In any case, except for plutonium oxides and organically-bound transuranics (not considered by the NRPB), the EPA values for gastrointestinal absorption are only twice the NRPB values. Although use of the EPA values rather than the NRPB values increases the dose estimate for the sources considered in this rulemaking, this would have a negligible effect on the final risk estimates because there is very little emission of transuranic radionuclides from the source categories considered, and the ingestion pathway as a whole contributes only a small fraction of the total risk.

Comment 5: (five) ... technical areas of AIRDOS-EPA, RADRISK and DARTAB where improvements may be required in the future:

a: " ... in the calculation of external dose, it was assumed that the deposited radioactivity stays on the surface of the earth for 100 years and never weathers into the soil. This assumption would seriously overestimate the dose from long-lived radionuclides." (Pages 22-23)

Response: The subcommittee is in error. A 100-year retention without environmental removal is not assumed in the calculation of external dose. Rather, EPA has assumed a 2% per year removal constant for deposition in rural areas and a 10% per year removal constant for urban areas. Removal of deposited radioactivity is of course highly dependent on such considerations as chemical form of the radionuclide soil composition and chemistry, and precipitation, irrigation and evapo-transpiration. The values we have used are comparable to those predicted by the model proposed by Hoffman and Baes[1] and those calculated from the changes in time of fallout products (^{137}Cs and ^{90}Sr) in food stuffs as reported by UNSCEAR[2]. A discussion of environmental removal from soil has been included in Volume I, Chapter 6 of the final BID.

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(1) Hoffman F.O. and Baes C.F. III, A Statistical Analysis of Selected Parameters for Predicting Food Chain Transport and Internal Dose of Radionuclides, NUREG/CR-1004, Oak Ridge National Laboratory, Oak Ridge, Tennessee 37831, 1979).

(2) United Nations Scientific Committee on the Effects of Atomic Radiation, Ionizing Radiation Sources and Biological Effects, 1982 Report to the General Assembly, with Annexes, United Nations, New York, 1982.

b: The documentation for AIRDOS-EPA also indicates that a constant absolute humidity value of 8 g/m^3 is used. Since absolute humidity is typically much lower than 8 g/m^3 in much of the U.S., this assumption leads to an underestimation of dose. It would be more appropriate, and not difficult, to use site-specific values for absolute humidity.

Response: This comment pertains to the assessment of the dose from tritium. While the Agency agrees that site specific values for the absolute humidity would be appropriate in cases where the dose from tritium would be particularly important for decisionmaking, this is not an important factor for the tritium releases considered in the draft BID. In the absence of site specific data, the Agency has followed the expert advice of Etnier, "a default value of 8 g/m^3 would yield dose estimates which are within a factor of two of the individual site specific data" (Etnier, E. L. "Regional Site Specific Absolute Humidity Data for Use in Tritium Dose Calculations").

The Agency has not analyzed, for this rulemaking, significant releases of tritium in areas of low humidity and precipitation, where 8 g/m^3 would be an inappropriate value. Rather, the only facility assessed that had significant release of tritium was the Department of Energy's Savannah River Facility in South Carolina. Etnier, cited above, calculates absolute humidity in South Carolina to be in the range of 9.1 to 10.2 g/m^3. Therefore, the Agency believes that the value used for the Savannah River assessment does not differ significantly from these values. However, we agree with the main thrust of the subcommittee's comment that site specific values should be used where they would significantly affect the result, i.e., in arid climates.

c: The physiological models and other input data required for the calculation of dose for internally absorbed radionuclides is equally important, and in many areas the data are incomplete. EPA should support work aimed at expanding the technical basis for many of the input parameters.

Response: The Agency is supporting work in this area by cooperating with other Federal agencies in the efforts of the International Commission on Radiological Protection to provide more complete and, particularly, age-specific data for dose calculations.

d: These three calculational programs do not now consider the important factor of uncertainty in each of the input parameters. The Subcommittee does not have specific suggestions as to how such data could be included, but believes that it is important for the EPA to develop methods that would indicate to the user the uncertainty or "noise" in the final values of REF. This uncertainty plays an important role in the setting of standards.

Response: The Agency agrees with the Subcommittee that a complete quantification of the effect of uncertainty in all of the input parameters on the final results is desirable. A methodology that utilizes a Monte Carlo approach to ascertain the probability distribution of the uncertainty is being developed by ORNL and others, in cooperation with the EPA, but it is unlikely to be useful for several years. Nevertheless, the final BID provides additional information on the degree of uncertainty in all components of the risk assessment.

e: Although scientifically sound, the units of REF are difficult for the lay person, or even the scientist, to grasp. Alternatively, consideration might be given to developing and using a common unit of risk that could apply to all radiation hazards and be more readily understood.

Response: The Agency agrees. In the final BID for the rulemaking (as in the draft BID), risks have been expressed in terms of the probability of inducing fatal cancer without reference to a risk equivalent factor (REF).

Comment 6: In estimating cancer risk, the ORP approach was weakened by the use of a single dose-response model, the linear nonthreshold model. A preferred approach would have been to present a range of models as discussed in the BEIR-3 report. (Page 24)

Response: The draft BID was based on the 1972 BEIR I report, which used only the linear nonthreshold model. Additional models described in the 1980 BEIR III report were discussed by EPA in "Basis for EPA Radiation Risk Estimates," prepared for the Subcommittee in January 1984. This report, which is incorporated into the final BID, presents the range of risk estimates obtained using all of the various dose response and risk projection models discussed in the BEIR III report.

Risk estimates in the final BID are not based on a single model of dose response, but include estimates made using the linear quadratic model as well as the linear model. The difference in estimated risks for these two dose response models is about a factor of 2.5. The reasons why the Agency selected these two models and rejected the BEIR III quadratic model are described in Chapter 8 of the final BID.

Comment 7: "The calculations of dose per unit intake of radioactivity apparently do not use an age-dependent factor." (Page 24)

Response: Age-dependent factors were used in the draft BID for estimating the risk due to radon progeny inhalation. Unfortunately, there are insufficient metabolic data for children to estimate age specific doses for all radionuclides. For the case of radon, the calculated lifetime risk obtained using age-specific data is 22% greater than that calculated using a dosimetry appropriate for adults only. The

Agency has developed, in conjunction with Oak Ridge National Laboratory, dosimetric models that will allow the inclusion of age-dependent factors for children when sufficient metabolic data becomes available. For a few radionuclides, including iodine-131, analyses of the risk using age dependent factors are made in the final BID. These results are then compared to the risks calculated using ICRP metabolic data for adults. The greatest increased risk based on age-dependent calculations was for lifetime exposure to I-131, which was 60% higher. However, until ICRP-23, "Reference Man," and ICRP-30, "Limits for Intake of Radionuclides for Workers," are revised to include physiological and metabolic data for children, it will not be practical to apply this approach to all radionuclides.

Comment 8: It was also not clear if, following radionuclide intake, the dose was assumed to be instantaneously delivered or protracted in time...the great detail of the life table approach is not matched by the details of the dose calculations. (Pages 24-25)

Response: The usefulness of the life table analysis is not confined to assessing the risk for time-dependent doses. In the EPA assessment, organ doses are not assumed to occur instantaneously, but are protracted over a period of time corresponding to the time each annual intake is retained within the body. Dealing with this type of exposure situation is one of the strengths of the life table approach. Moreover, the risk estimates derived by the BEIR III Committee are age-dependent and can be considered explicitly in our analysis only by using a life table approach. See also the prior comment.

Comment 9: Also, the fetus is generally considered to be very radiosensitive, but no calculation of in utero dose is made. (Page 25)

Response: The draft BID was based on the BEIR I report (NAS 1972). In that report, the cancer risk due to lifetime exposure at a constant dose rate of 100 mrem per year was calculated with and without in utero exposure. The difference in the estimated lifetime risk was small - 1 percent to 10 percent, depending on which risk model was used. In the final BID, presentations of estimates of cancer risk are patterned after those of the BEIR III Committee. The BEIR III risk estimates excluded the small risk from in utero doses because the Committee believed that the risk information was not sufficiently reliable for this age group. Moreover, as a practical matter, there is almost no information in the literature on the in utero dose from internal emitters in humans. Even though a complete analysis of in utero doses for all radionuclides is beyond the state of the art at this time, the final BID discusses in utero health effects in some detail.

Comment 10: Radiobiological data exist which indicate the likelihood that, at low doses and low dose rates, biological effects may be less than that suggested by a linear nonthreshold relationship. In

this regard, the radiobiological literature developed from experimentation using many different biological systems are a useful supplement to the human data, and ORP should examine this information and make greater use of it. (Page 25)

Response: The radiobiological data that the Subcommittee appears to be referring to are animal studies. While the Agency agrees that animal data can sometimes serve as a useful supplement to human data on radiation carcinogenesis, it does not believe decisions regarding the shape of dose response models should be based exclusively on animal data. The animal data have not been confirmed in studies of exposed humans and are, in fact, contradicted by some observations of radiogenic cancer in exposed humans. For example, the BEIR III Committee concluded that for breast cancer across a wide range from low to high doses, even with fractionation, and for thyroid cancer across a wide range of doses, the response was adequately described by a linear nonthreshold model.

H.I. Kohn and R.J.M. Fry (Radiation Carcinogenesis, N. Engl. J. Med. 310:504-511, 1984) recently pointed out, "Just what the shape of the curve should be for any human cancer risk awaits further investigation. When the mechanisms involved are unknown, there is not compelling reason to suppose that one type of curve or model will be superior to all others. In fact, it is likely that different decisive factors are at work in various situations, even if the initial biophysical step in each case is the same. Experiments have demonstrated how diverse dose-effect curves can be in the mouse for example, for the induction of a single class of reticular-tissue tumors: myeloid leukemia, roughly linear; thymic sarcoma, a negative slope to a reduction in incidence of 50 percent, followed by a plateau." It would appear that a single model based on "animals" is not predictive of response in a single species, much less being a universal model for many species.

The World Health Organization (WHO) has considered this problem in "Environmental Health Criteria 25" (WHO Geneva 1983) from a somewhat different viewpoint that is worthy of consideration.

> "466. In experimental animals and in man late somatic and hereditary effects may exhibit different shapes of the dose-effect relationships, according to a large number of physical and biological variables operating in each particular system. Linear, linear-quadratic, quadratic or complex relationships have been described in various circumstances. No generalization may be gained by the consideration of all existing experience, except perhaps that each specific system responds according to different kinetics of action and that biologically complex effects usually correspond to more complex types of relationships. It would be impossible to set up a rationale for a system of radiation protection by considering each case separately. To overcome this difficulty the assumption is made that late somatic and hereditary

effects of irradiation follow a non-threshold linear function of dose. This assumption is simple and there is evidence that it is also a conservative assumption in most cases."

Comment 11: The Subcommittee also believes that the use of the BEIR III report, which for cancer risks is based largely on human data at high doses and brief exposures, should be supplemented with other radiobiological data when extrapolations are made to very low doses accumulated over decades. The Subcommittee assertion is not intended as a criticism of the BEIR III panel's evaluation, for that report was not designed as a risk assessment for standard setting at very low level of exposure. (Page 26)

Reponse: The BEIR III Committee's report is entitled "The Effects on Populations of Exposure to Low Levels of Ionizing Radiation: 1980." Contrary to the Subcommittee's indication that the BEIR III Committee's report was not to be used in risk assessments for standard setting, the transmittal letter for this report to the Agency (page IV in NAS BEIR-3) from the President of the Academy clearly indicates otherwise, i.e., "We believe that the report will be helpful to the EPA and other agencies as they reassess radiation protection standards. It provides the scientific basis upon which standards may be decided after nonscientific social values have been taken into account." In this context, it is important to recognize that the term low level must always refer to dose rates that are at least 0.1 rad per year since this is the average yearly dose from naturally occurring background radiation in the United States. The Agency has assessed the size of incremental doses due to radionuclide emissions that are in addition to this background dose rate. We believe that the Academy envisioned the use of their risk estimates near background levels because the Federal Radiation Protection Guides published in 1960 apply to dose rates as low as 170 mrad per year. Further, the NAS studies were commissioned by EPA to help assess risks at levels near background. The radiological data the Subcommittee has identified is based on various animal studies. The Agency has considered animal data and other radiobiological information in its calculation of risk estimates. However, we do not believe it should be relied on more than human data when it is contradicted by studies of human cancer in exposed populations.

Comment 12: ... to assess the risk from radon daughters ...ORP again selected a single value, three percent lung cancer increase per WLM, as the relative risk coefficient. A range of values would have been more appropriate.... (Page 26)

Response: A range of values is used in the final BID. The draft BID used three percent because this is an average value for exposed miners (Indoor Radiation Exposure Due to Radium-226 in Florida Phosphate Lands, EPA 520/4-78-013, USEPA, Washington, D.C., 1978; V.E. Archer, E.P. Radford, and O. Axelson. Factors in Exposure-Response Relationships of Radon Daughter Injury, pp. 324-367 in Conference/Workshop on Lung Cancer

Epidemiology and Industrial Applications of Sputum Cytology. Colorado School of Mines, Golden, 1979). The report, "Basis for EPA Radiation Assessments" provided to the Subcommittee during its review compares six models for assessing the risk due to inhaling radon daughters. This information is also included in Chapter 8 of the final BID, along with corresponding risk estimates for representative models. While estimates of radon risk vary by about a factor of six, the UNSCEAR and ICRP models yield estimates within a factor of two of the EPA and BEIR III models. The BEIR III risk estimates for radon inhalation are nearly identical to those of EPA.

The more credible models included in the final BID are those of EPA, BEIR III, and AECB. All these models address lifetime risk for lifetime exposure as might be appropriate for a population.

The ICRP model addresses only exposure during the working lifetime and expression of cancer risk during a 30-year followup period, not appropriate for a population estimate.

The UNSCEAR model uses a lifetime exposure but only addresses cancer expression during a 40-year followup period. Such a short followup period is not really appropriate for a population estimate.

The NCRP model addresses lifetime risk for lifetime exposure. However, it assumes that the effect of exposure diminishes exponentially with a 20-year half-life. No scientific support for this assumption is currently available.

Comment 13: The Subcommittee is concerned that ORP uses the conservative or worst case linear extrapolation for carcinogenesis, i.e., extrapolation from acute high-dose exposures, while simultaneously using the chronic low-dose exposure extrapolation procedure for genetic effects. For genetic effects, the endpoint of concern is the nucleus. It is most likely that the nucleus is also the relevant target for important aspects of induction of somatic effects since scientists now recognize the role of oncogenes and chromosome rearrangement in carcinogenesis. Thus, state-of-the-art understanding of the mechanism of cancer induction can no longer justify ignoring "dose-rate effects" in favor of linear high-dose extrapolation. Scientific panels organized by the National Academy of Sciences, the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), the National Council on Radiation Protection (NCRP) and ICRP are in general agreement that some dose-rate effect occurs, and each of these groups uses this assumption in calculating best estimates. (Page 27)

Response: The BEIR III report provided dose-response estimates for three of the many possible models of dose-response. Of the three models the BEIR Committee evaluated, the linear model is most conservative. Even so, numerical risk estimates based on the linear model are within

the range of uncertainty of risk estimates based on the less conservative, linear quadratic model.

Although the linear model is generally conservative, it is clearly not a worst case model. There are a number of other dose-response models that would yield higher risks at low doses. For example, a model that takes account of the variation of radiosensitivity among members of a heterogeneous population would estimate the risk at low doses to be higher than the risk estimate from a linear model (Problems in Assessing the Cancer Risks of Low-Level Ionizing Radiation Exposure, U.S. General Accounting Office, 1981).

The Agency agrees that many scientists believe that reduced radiocarcinogenesis may be possible at low dose rates. These views are based on the body of evidence arising from cellular and animal studies. However, there is no human cancer data to support this view (H.I. Kohn and R.J.M. Fry, Radiation Carcinogenesis, N. Engl. J. Med., 310:504-511, 1984), and currently available studies of both radiogenic breast cancer and thyroid cancer in humans appear to contradict it. Breast cancer incidence has been shown to be linear in the dose range from less than 20 rad to more then 300 rad, with no sign of a quadratic term at high doses. Moreover, when the dose to breast tissues is fractionated into many small doses, less than a rad, the cancer risk is not reduced, contrary to the effect that would be predicted in a dose-rate effect. Similarly, thyroid doses of less than 10 rad are as carcinogenic per unit dose as are much larger doses, a few hundred rad. While these examples indicate that the linear model may not overestimate risks for some types of cancer, EPA does not believe that all types of radiogenic cancers will necessarily follow the same dose-response model. The final BID includes risk estimates based on reducing radiocarcinogenesis at low dose rates for low LET radiations. This will enable the public and Agency decisionmakers to observe the significance of using alternative dose response models. In general, whether one uses the linear model or the model that reduces risk for low dose rates, the difference in risk estimates is a factor of 2.5. Even so, the Agency believes that it is reasonable and prudent to give considerable credibility to estimates based on a linear response since this model has the least conflict with the data observed from human cancer studies.

Comment 14: In addition, in cases where ORP proposes to use a years of life lost estimate per rad exposure for calculating the risk of somatic effects, a parallel approach should be applied to deriving a statement of genetic risk (see UNSCEAR 82). (Page 27)

Response: Although the Agency presented a method for calculating the average number of years of life lost due to premature cancer deaths in its presentation to the Subcommittee, it did not include such results in either the draft or final BID. Although analyzing years of life lost due to premature cancer death is an interesting concept, EPA has not

attempted to incorporate it into decisionmaking. It is premature to develop similar estimates for genetic effects until more complete information on reduction in life expectancy, severity of impairment during the life span, and impact on family and society for a large variety of genetic effects (or "endpoints of genetic effects") is published. The Agency notes that the 1982 UNSCEAR report stressed the uncertainty of its estimates of years of life lost and years of life impaired for genetic effects, and the virtual absence of estimates for irregularly inherited conditions or recessive conditions.

Comment 15: Finally, BEIR III estimates for genetic effects are low because the mouse female data are inappropriate for human extrapolation. The immature mouse oocyte cannot be used to detect mutations since an ionization traversal through the cell membrane kills the cell (Dobson, 1983). Faced with this scientific uncertainty it would be judicious for ORP to also give an alternative estimate, assuming equivalent mutability for both sexes, until there is other evidence to the contrary. (Page 27 and 28)

Response: EPA has included alternative estimates in the final BID that assume equal mutability for both sexes. These alternative estimates of genetic damage are about 40% larger than those in the BEIR III report, where the female is considered to be 60% less sensitive to mutations than the male. This change is small compared to the range of uncertainty in the BEIR III estimates for genetic effects which may be several hundred percent.

Comment 16: ORP's selection of relative versus absolute risk models for estimating cancer risks is another instance where a more detailed analysis and presentation would have been useful. Both approaches have their strengths and weaknesses which should have been elaborated. If one approach was to be selected over the others then it would be appropriate to clearly document why it was selected and how it is reflected in the uncertainty of the final risk estimates. (Page 28)

Response: Absolute and relative risk models are discussed in the Final BID in two aspects: as transportation models for use in applying risks observed in one group to another having different demographic characteristics and as risk projection models for estimating the lifetime risk from radiation exposure beyond the years of observation. The limitations introduced by the selection of a particular model are discussed in the Final BID, along with the degree of uncertainty inherent in the Agency's use of an average of relative and absolute risk projections for all cancers except leukemia and bone cancer. The choice of a relative or absolute risk population model is not important for leukemia and bone cancer because the duration of expression is apparently less than the period of observation in epidemiological studies. In such cases, either model yields the same estimated risk, as noted in the Final BID.

Comment 17: The factor of twenty for high LET radiation appears appropriate when used by ICRP and inappropriate when used by ORP. ICRP has a dose-rate factor for low LET radiation. In contrast, ORP uses a high dose rate for low LET to compare with high LET. The factor of twenty is thus too great. (Page 28)

Response: The Agency agrees. In the draft BID, the Agency followed the same procedure as then used by the BEIR III Committee, in which the risk of alpha emitters was divided by 20 to estimate low LET risks using a linear model. However, EPA agrees that risk estimates based on the ICRP quality factor of 20 and risks observed for acute low LET exposures should take account of a dose rate effectiveness factor (DREF). Risk estimates for internally-deposited alpha particle emitters have been revised in the final BID to reflect the information supplied by the Subcommittee, i.e., risk estimates for internally-deposited alpha particle emitters are twenty times the risk estimated using the BEIR III linear dose response model, and a DREF of 2.5.

The comments by the Subcommittee on pages 28 and 29 were the result of a misconception on the part of the Subcommittee. Subsequent discussion with the Subcommittee member who made the comment indicated that he thought that the arguments made by EPA in developing an RBE of 20 for genetic effects due to alpha radiation were the basis for the quality factor of 20 the Agency used to estimate the risk of carcinogenesis due to alpha radiation. This is not the case. The EPA analysis of the RBE for genetic effects is independent of the ICRP choice of a quality factor of 20 for carcinogenesis due to alpha radiation. Both the RBE for genetic effects the ICRP quality factor apply to the risk of alpha radiation compared to low dose rate low LET radiation. For genetic effects, the BEIR III Committee (and EPA) used a dose rate effectiveness factor (DREF) of 3. The Subcommittee agreed with this choice for genetic effects. The SAB Subcommittee informed EPA that the ICRP had used a DREF of 2.5 in developing their cancer risk estimates for low dose rate low LET radiations and that their choice of a quality factor of 20 was based on this assumption. Cancer risk estimates for alpha particle emitters in the final BID were recalculated accordingly.

3.0 COMMENTS ON THE SCIENCE ADVISORY BOARD SUBCOMMITTEE FINAL REPORT ON RISK ASSESSMENT

This section responds to comments received from the general public related to the Science Advisory Board Subcommittee report on risk assessment.

Comment 3.1.a: The commenters agree with the SAB comments that the proposed regulations lack a scientifically adequate basis for regulatory decisions for radionuclides and that a risk assessment document must be completed and submitted for review. (I-1, I-6, I-8, I-11)

Comment 3.1.b: Commenter supports SAB recommendation that EPA prepare a range of risk estimates in future work regarding NESHAPS for radionuclides and more clearly delineate its risk assessments from its risk management decisions. (I-3)

Response (Comments 3.1.a and b): These comments have been addressed in Section 2.1. The appropriate sections are indicated below:

Comment 3.1.a - See response to Recommendation Numbers 2, 3, 4, and 5.

Comment 3.1.b - See response to Recommendation Numbers 1, 2, 3, and 4.

Comment 3.2a: The suggestions of the Science Advisory Board go beyond their mandate and should not be allowed to impede prompt completion of the Agency's obligations to produce final standards. (P-6)

Comment 3.2b: The report authored by the Science Advisory Board should be excluded from consideration when considering the final national emission standards for radionuclides. (P-5)

Response (Comments 3.2a and b): The SAB was charged with a review of the Agency's risk assessment methodology. That review was to focus on such items as identifying the health hazards from exposure to radiation, analyzing the movement from sources through various pathways, estimating a dose received by humans, calculating the probability of health effects, and presenting a statement of uncertainty in the risk estimates. The Committee, in some instances, focused and commented on risk management which includes such things as comparing the risk estimates to risks from other hazards to assist in judging significance, developing alternate control strategies, analyzing the social and economic aspects of the status quo and alternative actions, and deciding on an appropriate course of action.

The Agency separated the risk assessment issues and comments from the risk management issues and comments and considered only the former in arriving at its decisions.

Comment 3.3: The Science Advisory Board Subcommittee's recommendation that EPA abandon the ALARA regulatory approach in favor of the "probable risk" approach is beyond the Subcommittee's mandate to consider only the scientific basis of EPA's risk assessment and is contrary to both the Clean Air Act and the tenets of radiation protection. (P-6)

Response: The Agency agrees. The discussion of ALARA as the basis for decisions is clearly a discussion of a possible approach to risk management. It was the charge of the SAB to review the Agency's risk assessment methodology.

Comment 3.4: Commenter requests EPA to reconsider and withdraw the listing of radionuclides as hazardous air pollutants. This is based on the SAB Subcommittee report which states: (I-2)

> ... the health impacts from radioactive emissions being discharged from all the U.S. facilities ... were calculated to be much less than one cancer per year for the entire country.

Response: The record strongly supports the conclusion that radionuclides meet the criterion for a hazardous air pollutant in Section 112 of the Act because extensive scientific evidence indicates that exposure to radiation increases the risks of developing fatal and nonfatal cancers. This information is based on animal and human studies at levels only a few times greater than potential environmental concentrations. Therefore, the original decision to list radionuclides as a hazardous air pollutant is adequately supported.

Comment 3.5: The SAB has confirmed that EPA's proposal to regulate airborne radionuclides lacks any scientifically adequate basis for regulatory decisions for this pollutant; therefore, commenters suggest that EPA should withdraw the proposed rule. (I-1, I-4, I-10, I-11, I-12)

Response: The Agency announced its withdrawal of four proposed standards for radionuclide emissions under Section 112 of the Clean Air Act and affirmed its original decisions not to regulate emissions from the other five source categories considered. The announcement and reasons for the action appear in the Federal Register.

Comment 3.6: EPA's risk assessment should emphasize "upper bound" estimates, rather than "central" estimates, as recommended by the Science Advisory Board Subcommittee.

Response: This commenter has also said, "We do not object to a risk assessment document that displays a range of models or assumptions, along with their resulting risk assessments." In the Background Information Document, EPA considered several models. The Agency did not attempt to arrive at a "central" estimate, through some sort of averaging procedure.

EPA does not agree that it must always select the model that yields the highest risk estimates, for an "upper bound" on risk. See the response to Comment 2.2.1f in Volume 1 of this document.

4.0 UNDERGROUND URANIUM MINES

Comment 4.1: Neither the information in the original docket nor the new information recently added justify regulation of radon from uranium vents at the standard proposed by EPA. (I-2)

Response: The Agency proposed a standard that would limit the annual average radon-222 concentration in air due to emissions from an underground mine to 0.2 pCi/l above background in any unrestricted area. The standard was expected to be met by one of the following procedures: (1) reducing the percentage of time the mine operates, (2) increasing the effective height of the release, or (3) controlling land around the mine. EPA expected that mine operators would most likely try to control land within about 2 kilometers of the mine vents in order to comply with the standards. EPA did not choose to issue a direct emission standard for radon from underground uranium mines because available information suggested that radon could not be collected by available pollution control equipment before being released from the vents and reductions afforded by better bulkheading or sealants were highly uncertain. Comments on the proposed rule indicated that controlling land around the mine might not be feasible because private owners of land surrounding the mine might be unwilling to make their land available to the mine owners or might be willing to sell only at prices higher than fair market value.

Analysis of the likely reduction in health risks afforded by the proposed standards showed that while risks to nearby individuals were reduced by a factor of about 10, the risks to the total population were only negligibly reduced. The lack of population risk reduction was due to the fact that radon releases would not be mitigated, they would only be more widely dispersed.

Several comments were received stating that the EPA had overestimated the risks from radon-222 emissions from underground uranium mines. It was suggested that the Agency had used overly conservative assumptions in the dispersion and risk calculations and that it used greater risk coefficients than recommended by other recognized radiation experts. EPA has reevaluated the risk estimates from radon-222 emissions and revised the parameters used for emission rates, plume rise, and equilibrium ratios. Estimates of the lifetime risks to individuals living near these mines range from one in one thousand to one in one hundred. The potential exists for even higher risks in some situations, e.g., a person living very close to several horizontal mine vents or in areas influenced by multiple mine emissions. Lifetime risk in these situations can be as high as one in ten. The fatal cancer risk to the total population, both regionally and nationally, is 5 fatal cancers/year. The Agency considers these risks to be significant and believes action is needed to protect populations and individuals living near underground uranium mines.

Because radon-222 is a noble gas and the volume of air discharged through mine vents is very large, there is no practical method to remove radon-222 from the mine exhaust air. Absorption onto activated charcoal is the most widely used method for removing noble gases from a low volume air stream. However, application of this method to the removal of radon-222 from mine ventilation air at the volumes of air which must be treated would require large, complex, unproven systems which would be extremely costly. Therefore, it is the Administrator's judgment that it is not feasible to prescribe or enforce an emission standard for radon-222 emissions from underground uranium mines because radon-222 cannot be emitted through a conveyance designed to capture the gas under current conditions. Instead, EPA has decided to begin development of work practice, design, equipment, or operation standards to control radon releases from underground uranium mines.

To this end, EPA has issued an Advanced Notice of Proposed Rulemaking to acquire information/data in a number of subject areas. The Advanced Notice of Proposed Rulemaking (ANPR) on this subject solicits information in the following areas:

(1) amounts of emissions of radon-222 from underground uranium mines;

(2) applicable design, equipment, work practice or operational standards;

(3) ability to predict releases of radon from underground uranium mines without controls and with various types of bulkheads, sealants, or other controls;

(4) effectiveness, feasibility, and costs of such controls; and

(5) estimates of impacts on nearby individuals and populations due to radon-222 emissions before and after such controls.

Comment 4.2a: Additional evidence supports the conclusion that technology is available to allow uranium mines to achieve significantly more stringent emission limitations for radon than those proposed by EPA. (P-2)

Comment 4.2b: EPA fails to consider radon exposure from mines in the context of total exposure to all major sources of radon. (P-2)

Comment 4.2c: EPA should set its standard at a level which will avoid any increased deaths attributable to radon from uranium mines when considered as part of the total radon exposure above natural background experienced by a person living in uranium mining districts. (P-2)

Response (Comment 4.2a through c): EPA has issued an Advanced Notice of Proposed Rulemaking for uranium mines. The Agency has solicited

information in a number of subject areas, including radionuclide emission levels and control options and strategies (also see response to Comment 6.1). These data will be used to develop work practice, design, equipment and/or operational standards to control radon releases from uranium mines. It is the Agency's intent to evaluate the risk of radon exposure in the context of total exposure to all major sources, including exposure in the home.

Comment 4.3: Any standards for underground uranium mines should be developed to protect actual individuals from actual exposure that could produce significant risks of harm. Similarly, any exemption program should be based on the same conditions. In short, if no real individual is subject to such exposures, imposition of standards is unnecessary. (I-2)

Response: The main concern in this comment seems to be that the method does not relate to actual people. In the final BID, maps are included to show where individuals are located near mine vents.

Comment 4.4: Commenters state that release data are outdated and that many mines are now closed. (I-2, I-6)

Response: Estimates of emissions were revised on the basis of mine age and size in 1982. This methodology is described in Volume II of the Background Information Document.

Comment 4.5: Commenters state that costs of controls for underground uranium mines are prohibitive. (I-2, I-6)

Response: The cost for controls has been updated in the final BID. These costs will be reconsidered when the Agency examines the feasibility of a work practice standard. See also response to Comment 4.1.

Comment 4.6: The Gaussian dispersion model is very conservative and its level of uncertainty in rough terrain is unknown; the relevance of the model mine in areas of multiple mines is questionable; the radon emission data for the Ambrosia Lake area are dated; Droppo's comments on the importance of plume rise, vent orientation, and local meteorology are well taken. (I-2)

Response: In response to this comment, EPA has changed the model used to estimate radon concentrations in air. The model now used (developed by Droppo) is better able to predict the influence of multiple mines (see Volume I of the Background Information Document).

Comment 4.7: EPA should compare the risk of lung cancer associated with radon releases from uranium mines against the risk of lung cancer from natural background causes, not against the risk of lung cancer associated with preventable exposure to anthropogenic agents, such as cigarette smoking. (P-2)

Response: EPA disagrees. Between 1 and 3 percent of fatal cancers have been attributed to the natural radiation background. This risk is significant (approximately 2 in 1000). EPA has concluded that the level of risk associated with background radiation should not be judged acceptable just because it is unavoidable. Therefore, the natural radiation background is not a good benchmark for hazardous material emission limits that are intended to be protective of public health with an ample margin of safety.

5.0 ELEMENTAL PHOSPHORUS PLANTS

All of the comments included in this Section relate to the following reports prepared by Midwest Research Institute for EPA: (1) Analysis of Achievable Po-210 Emission Reductions and Associated Costs for FMC's Pocatello, Idaho, Plant and (2) Analysis of Achievable Po-210 Emission Reductions and Associated Costs for Monsanto's Elemental Phosphorus Plant at Soda Springs, Idaho.

5.1 SAMPLING LOCATIONS/PROCEDURES

Comment 5.1.1: Monsanto commented that no control system inlet sampling was performed so no control efficiencies could be calculated (I-10).

Response: The control efficiency of the existing scrubber was not necessary for estimating the emission reductions that could be achieved with add-on scrubbers, baghouses, or ESP's. It was assumed that the existing emission control devices would continue to be operated and that new control devices would be added to the exhaust gas stream of the existing control devices. Therefore, testing only the outlet was needed to estimate performance that could be achieved with new control devices.

Comment 5.1.2: Monsanto commented that since the outlet sampling location did not meet EPA Reference Method 1 criteria, the usefulness of the data is limited and adequate only for relative comparisons (I-10).

Response: The sampling data obtained at the Monsanto plant are, under the circumstances, acceptable for the purpose of estimating of the Po-210 emissions. As indicated in Section 6.3.4 of the final BID, the sampling location at the Monsanto plant was not adequate for particle size measurements. Therefore, particle size distributions measured at the FMC plant were used to estimate particle size distributions for the Monsanto plant (see response to Comment 5.2.1 below).

5.2 PARTICLE SIZE

Comment 5.2.1: Monsanto commented that the SASS and Anderson particle size distribution methodologies are incompatible for comparison purposes (I-10).

Response: To estimate particulate emissions and the Po-210 associated with the particulate emissions from Monsanto, it was assumed that the distribution of particle size and the distribution of Po-210 associated with the particles would be the same at Monsanto as it was at FMC. The comparison of data from the SASS and Andersen trains merely showed that the particle size distributions were not grossly different.

Comment 5.2.2: Monsanto commented that the extrapolation of the particle size distribution below 0.6 micrometer (μm) for the Anderson impactor, and below 1 μm for the SASS train is without merit (I-12).

Response: Extrapolation of data, such as particle size distribution, is commonly used in the design of pollution control equipment. The extrapolation of particle size data is reasonable for estimating the performance that can be achieved by properly designed and properly operated pollution control equipment.

Comment 5.2.3: FMC, in the attachment to its comment letter, noted that size distribution curves are typically plotted as a logarithmic normal function. They comment that the plot in the report minimizes the percentage of particles in the less than 0.1 μm fraction (I-12).

Response: The plot presented in the report is of actual data and was not extrapolated to smaller particle sizes.

Comment 5.2.4: FMC, in its attachment, commented that assuming that the Po-210 is evenly distributed over the respective size fractions overstates the predicted control efficiency (I-12).

Response: There are no data to show just how the Po-210 is distributed across each size fraction. In the absence of such data EPA has assumed a uniform distribution of Po-210 over particle size ranges. EPA believes that the assumed distribution is as likely as any other distribution.

5.3 DEMONSTRATED TECHNOLOGY

General

Comment 5.3.1: FMC contends that none of the proposed technologies are demonstrated. Both Monsanto and FMC suggest that pilot scale testing of the technologies would be required prior to full scale installation (I-10, I-12).

Response: None of the control technologies evaluated are either emerging or novel applications. The scrubber pressure drops evaluated are well within the range of those used in other industrial applications. In addition, this industry is familiar with scrubber technology, albeit at lower pressure drops. Wet ESPs are used in a variety of industries, including one in this industry. Fabric filters, while not used in this industry, are widely used for fine particulate control in other industries, including on sources having saturated, or near saturated, exhaust streams. EPA would not argue against pilot scale testing of these technologies. It was not the purpose of EPA's study to provide an exact engineering job, complete with site study, such as would be required for ultimate installation. However, both EPA and MRI

representatives were on-site during the period of the test program. During this visit, observations were made of the facility and its layout. These observations were used in the analysis.

Comment 5.3.2: Both Monsanto and FMC contend that no technology has been shown that will meet the 1 curie/year proposed standard (I-10, I-12).

Response: The purpose of the study was to analyze what emission level could be achieved at what cost at the two facilities. The analysis was based on the use of existing control technology operating within reasonable process bounds. This analysis showed that significant reductions in Po-210 emissions could be achieved through the use of additional control equipment.

Wet Scrubbers

Comment 5.3.3: Monsanto commented that the Calvert model was used with an empirical factor, f, equal to 0.5. The factor appears to be high, thus, overstating scrubber efficiency (I-10).

Response: The factor f has a value of 0.5 for full scale scrubbers on industrial sources of air pollution and, thus, is appropriate for this modeling effort.[1,2] There is no data to indicate that it is inappropriate.

The f values may range from a low of 0.10 to a high of 0.70 with typical values in the range of 0.25 to 0.50.[3] For hydrophobic particles (lacking affinity for water), an f value of 0.25 is recommended.[2] For hydrophilic particles (with strong affinity for water), f values are significantly higher (0.4 to 0.5).[2]

Comment 5.3.4: FMC noted that there are significant uncertainties in the prediction of collection efficiency. The assumptions of f factor and particle density could be 20 percent high and together could introduce a 20 percent error in estimated penetration. The calculation also relies on a droplet size correlation developed over 40 years ago by Nukiyama and Tanasawa (I-12).

Response: The factors noted should be considered to properly design equipment to meet the emission levels that have been estimated. Small variations in these values do not change the estimate of what can be achieved by properly designed and operated control equipment.

Wet Electrostatic Precipitators

Comment 5.3.5: Monsanto and FMC noted that emission tests were performed on a wet ESP at one plant and the particle size distribution at another plant was used. MRI selected a precipitation rate parameter (w) based on one plant using a different type of calciner. It is unlikely

that the precipitation rate parameters are the same and it is unlikely that the Deutsch-Anderson equation accurately predicts performance for this particle size distribution, which is generally smaller than 0.5 μm (I-10, I-12).

Response: The precipitation rate parameter (w) is influenced by the characteristics of the dust, including particle size and resistivity. An effective precipitation rate parameter is commonly used that is based on field experience rather than theory. Using field data (which included particles less than 0.5 μm in diameter), a value of 5 ft/min for the precipitation rate parameter was calculated for the smallest particle diameter (i.e., 0.35 μm). The Cunningham Correction Factor was used to adjust the precipitation rate parameter for particles smaller than 5 μm.[4]

The properties of the gas and particulates at the two evaluated plants are similar to those at the plant using the wet ESP. Therefore, for estimating what can be achieved by properly designed control equipment, it is reasonable to use the precipitation rate parameters (based on actual data) for both plants. To actually design the control equipment, a plant may wish to use data that is specific to that plant.

Comment 5.3.6: FMC commented that there is uncertainty and variability in expected collection efficiencies using the Deutsch-Anderson equation. Even more elaborate models are also entirely theoretical resulting in difficulties in predicting actual efficiency (I-12).

Response: The Deutsch-Anderson equation is commonly used for estimating particle collection efficiency. Factors such as particle reentrainment, gas leakage, and the physical and chemical properties of the particles and gases are often unknown and cannot be accounted for in an analysis. The equation and analysis performed is typical of procedures used to predict collection efficiencies.

Fabric Filters

Comment 5.3.7: Monsanto commented that the application of fabric filter technology to their Soda Springs, Idaho, facility would require extensive research and analysis to demonstrate the level of emission reduction claimed in the report. FMC commented that fabric filters (in particular, fabric filters controlling exhaust gas streams from wet scrubbers) do not represent a demonstrated control technology for reduction of Po-210 emissions and that pilot plant testing would be required to verify the fabric filter efficiency projected in the report (I-10, I-12).

Response: The MRI analysis of fabric filter performance was based on the application of conventional fabric filter technology to a gas stream whose characteristics had been determined through testing. This approach was adequate to develop an estimate of the cost to reduce Po-210 emissions from phosphate rock calciners.

The application of fabric filter technology to control particulate emissions from mineral processing industries is well-established and has been studied extensively. However, EPA agrees that the elemental phosphorus manufacturing industry has no direct experience in the use of fabric filters to control Po-210 emissions from moisture-laden gas streams. Therefore, pilot scale testing may be required to optimize design and operating parameters for a fabric filter in this application (see response to Comment 5.3.1).

Comment 5.3.8: FMC commented that the report contains no data to establish the collection efficiency of a fabric filter when collecting particles less than 0.5 μm in diameter. FMC also noted that the report does not discuss the uncertainty and variability of expected collection efficiency by a fabric filter. (Related comments by a private consultant to FMC state that the report reinforces the hazards of using particle size distribution data on fine particles to predict collection efficiency. This consultant states that MRI applied a 97 percent collection efficiency to particles less than 0.5 μm in diameter when the data do not extend below 0.2 μm. He further states that between 30 and 80 percent of the particles in question are less than 0.2 μm in diameter.) (I-12)

Response: No reliable *in situ* sampling techniques exist to measure particle size when the particles are less than 0.3 μm in diameter. MRI utilized the best information available when projecting the performance of a fabric filter on fine particles at the FMC plant. The expected collected efficiency used in the MRI analysis is consistent with observed collection efficiencies of fabric filters in other mineral industries.

Insufficient data exist to analyze the uncertainty and variability of the expected collection efficiency of a fabric filter on this application. Collection efficiency can vary as a result of numerous design and operating parameters (air-to-cloth ratio, pressure drop, cleaning frequency, cloth type, cleaning mechanism). The predicted collection efficiency is based on the best available information for this application using a control technology that is well established on similar sources of particulate emissions.

The statement by FMC's consultant that 30 to 80 percent of the particles are less than 0.2 μm is inconsistent with FMC's comment that the particle size distribution below 0.5 μm in FMC's stack emissions is unknown. Further, the source of this consultant's data is not identified, and these data did not come from the MRI report.

Comment 5.3.9: Monsanto commented that MRI did not consider what happens to Po-210 in the presence of a gas flame during reheating of the exhaust gas from a wet scrubber before the gas enters a fabric filter. Monsanto noted that Po-210 could vaporize and not be collected by the fabric filter (I-10).

Response: The scrubber exhaust gas is heated by a natural gas-fired burner to increase its temperature from 145°F to approximately 200°F to prevent moisture from condensing on the fabric filter bags. The scrubber exhaust gas stream does not pass through a direct flame; the burner is not in-line with the gas flow, external combustion air was provided, and the flame would not be in direct contact with the Po-210. Therefore, volatilization of Po-210 should not occur. Even if Po-210 did volatilize during the indirect heating of the scrubber exhaust gas, the gas temperature at the fabric filter bags is approximately 200°F. Therefore, any Po-210 that had been vaporized upstream would recondense at the lower temperature and would be captured as particulate matter by the fabric filter.

Comment 5.3.10: FMC commented that fluoride emissions would be 2.5 times the allowable limit if 14 percent of the calciner exhaust gas bypassed the wet scrubber and was used to reheat the inlet gas stream to a fabric filter. FMC stated that all of the calciner exhaust gas would need to be ducted to the scrubber for fluoride control and then be reheated to prevent bag binding in the fabric filter (I-12).

Response: Calciner exhaust gases must be scrubbed to remove fluoride at this facility to meet the State ambient air standard for fluorides. MRI has revised the design of the control system at this facility accordingly and has developed the capital and annualized costs for a natural gas-fire burner to heat the entire exhaust gas stream from the wet scrubber. These costs are shown in response to Comment 5.4.9.

5.4 COSTS

General

Comment 5.4.1: Monsanto and FMC commented that EPA has underestimated the cost of controls for reducing Po-210 emissions at elemental phosphorous plants by a factor of 3 or 4. Costs have been underestimated for a number of reasons but primarily because of the use of carbon steel rather than stainless steel for the equipment (I-10, I-12).

Response: EPA disagrees that is has overestimated these costs by a factor of 3 or 4. A reevaluation of the cost estimates by MRI, taking into consideration the comments received and using more conservative assumptions in the calculations (so as not to underestimate costs) shows annualized cost increases of no more than a factor of 2 (see Tables 5.1 and 5.2).

TABLE 5.1 SUMMARY OF REVISED RESULTS FOR THE ROTARY KILN CALCINER--MONSANTO

Control technology	Original Capital costs,[a] $	Original Annualized costs,[a] $/yr	Revised Capital costs,[a] $	Revised Annualized costs,[a] $/yr
Scrubber				
15 in. ΔP	1,090,600	879,800	3,005,600	1,238,200
30 in. ΔP	1,455,400	1,405,800	3,494,600	1,807,000
45 in. ΔP	1,989,400	1,954,600	4,217,600	2,425,800
ESP				
200 SCA[b]	2,851,200	782,800	6,297,500	1,431,300
300 SCA	3,182,400	861,600	7,735,900	1,585,300
400 SCA	4,330,200	1,065,800	10,538,100	2,050,000
Fabric Filter	4,147,900	1,286,900	6,078,600	1,784,700

[a]Based on January 1984 dollars.
[b]SCA = Specific collection area in ft^2/1,000 acfm.

TABLE 5.2 SUMMARY OF REVISED RESULTS FOR CALCINER NO. 2--FMC[a]

Control technology	Original Capital costs,[b] $	Original Annualized costs,[b] $/yr	Revised Capital costs,[b] $	Revised Annualized costs,[b] $/yr
Scrubber				
15 in. ΔP	1,032,000	792,000	2,166,200	1,017,600
30 in. ΔP	1,377,000	1,270,000	2,628,600	1,526,800
45 in. ΔP	1,870,000	1,769,000	3,291,400	2,099,800
ESP				
200 SCA[c]	2,596,000	699,000	6,512,600	1,318,700
300 SCA	2,949,000	771,000	7,374,800	1,470,800
400 SCA	3,346,000	868,000	8,344,800	1,657,900
Fabric Filter	3,672,000	927,000	6,921,900	1,945,200

[a]Total costs for both calciners can be estimated by doubling the Calciner No. 2 values.
[b]Based on January 1984 dollars.
[c]SCA = Specific collection area in ft^2/1,000 acfm.

In preparing a regulatory impact analysis (EPA 520/1-84-025) for emission standards for elemental phosphous plants, EPA analyzed the regulatory impact of higher costs than those included in the MRI reports. Therefore, the Agency has already considered how somewhat higher costs would affect these plants. More specific responses to comments on costs follow below.

Comment 5.4.2: Monsanto commented that their experience with the GARD manual, which was the basis for the costing, has been that the resulting cost estimates are significantly lower than actual costs, especially when devices are being added to an existing system (I-10).

Response: The GARD manual is accepted, and used, by the EPA for estimating the costs of air pollution control systems. These costs are typically accepted to have a ±30 percent error range. It is recognized that site-specific factors may influence the costs to a large extent. However, the manual, and the resulting costs, are valuable for providing a consistent basis for comparing various control options. Methods are available to update the costs to any period desired and these methods were followed in preparing the Monsanto and FMC reports.

Comment 5.4.3: Monsanto commented that the costs presented by MRI did not include costs for fabrication labor, foundations, supports, contingencies, or engineering (I-10).

Response: As noted later in Monsanto's comment letter, the GARD manual uses a modified "Lang Method" approach to cost estimating. This approach applies cost factors for installation to the cost of equipment. Factors for all of the items noted by Monsanto are included and, therefore, were utilized in the cost estimates.

Comment 5.4.4: Monsanto questioned as being low the $16/ton value used for waste disposal if the material were to be classified as a hazardous waste (I-10).

Response: The $16/ton value noted by Monsanto is a 1978 value obtained from information gathered by the EPA on a variety of sources. It was updated to $23.50/ton (January 1984 dollars) for use in estimating the costs. The disposal cost was used as a what-if, conservative estimate. Some plants, including Monsanto, recycle the wastes to the process, thus eliminating the waste disposal costs. In any case, waste disposal costs would be relatively small compared to the total annualized costs.

Comment 5.4.5: Monsanto and FMC both commented that MRI understated the capital costs of the control technologies by a factor of three to four. The primary reason for the understatement of costs was the use of carbon rather than stainless steel for the equipment. (Other factors were

also noted for each control device. These factors will be addressed in later sections.) The commenters believe carbon steel to be unacceptable because of corrosion problems (I-10, I-12).

Response: The commenters are correct in stating that carbon steel was used in the cost analyses. However, as noted in the response to Comment 5.4.7, certain other considerations were taken to account for the corrosion problem.

The commenter's allegation that carbon steel is unacceptable and that stainless steel is preferred is not supported in the literature. In a list presented in the McIlvaine Scrubber Manual, 316 stainless steel carries a lower rating that does carbon steel for use with hydrofluoric acid (i.e., 316 stainless steel is considered unsatisfactory for use while carbon steel is suitable for limited service).[5] The recommended materials for use with hydrofluoric acid are plastics (e.g., epoxy resins). These compounds are also higher rated for use with sulfuric acid. Thus, epoxy-lined carbon steel would provide better corrosion resistance than would 316 stainless steel. The cost of epoxy lining is addressed in the response to Comment 5.4.7.

Comment 5.4.6: FMC indicated that an 11-year life should be used in determining the capital recovery factor rather than 20 years as done in the MRI analyses. They indicated that 11 years is currently accepted as book life and approximates actual equipment life (I-12).

Response: Using the 11 year life rather than 20-year life would increase the capital recovery factor from 11.746 percent to 15.396 percent. While this is a 31 percent increase in the value of the capital recovery factor, it only translates into a 5 to 14 percent increase in the annualized cost using the cost values reported in the August 1984 report for FMC. With epoxy-lined components, a 20-year life is believed appropriate. EPA analyzed the effect of a 10-year life on the annualized costs of these control systems in a regulatory impact analysis (EPA 520/1-84-025).

Wet Scrubbers

Comment 5.4.7: Both commenters stated their concern that the capital costs of wet scrubbers are understated for a variety of reasons but primarily as a result of the use of carbon steel (I-10, I-12).

Response: In its initial analysis, MRI costed the use of a rubber liner for the carbon steel Venturi scrubber for corrosion resistance. Although rubber is also listed in the McIlvaine Scrubber Manual as being unsatisfactory for use with hydrofluoric acid, its cost range is the same as that for epoxy.[6] Thus, the cost of corrosion resistance has been accounted for.

However, in responding to these comments, both the basis and the estimated costs for a Venturi scrubber at these facilities have been

reexamined. The cost factors utilized in the "Lang Method" can be adjusted depending on the circumstances. Tables 5.1 and 5.2 present the revised costs for Monsanto and FMC, respectively. Liner costs have been calculated per square foot where possible. Where the area cannot be determined, the costs have been increased by 15 percent (the maximum percent of liner cost versus wet scrubber cost).

Wet Electrostatic Precipitators

Comment 5.4.8: Again both commenters noted their concern about the understatement of costs and the use of carbon steel (I-10, I-18).

Response: Wet ESPs were included in the reexamination of the control device costs. The revised costs are included in Tables 5.1 and 5.2. The multiplier for wet vs. dry ESPs has been increased from 1.15 to 2.0 to more adequately account for lining and corrosion protection. The revised values may more accurately reflect estimated costs.

Fabric Filters

Comment 5.4.9: Both commenters expressed their concern regarding the understated costs and the use of carbon steel. Monsanto commented that reheat of the gas stream will lead to slagging and that the heat requirement calculations do not account for heat losses. Monsanto also provided information as to their natural gas costs and altitude. Additional comments by Monsanto relate to the use of V-belt drives in the calculations. Monsanto also contends that no provision was made for mixing the two streams.

FMC commented that the gas volume to be treated has been understated. The cost of the baghouse is alleged to be understated because of the use of the reheat bypass stream. FMC also contends that an air-to-cloth ratio (A/C) of 2:1 would be more appropriate than the selection of 4:1 (I-10, I-12).

Response: Revised costs for fabric filters are included in Tables 5.1 and 5.2. In costing a fabric filter for use on these gas streams, it was assumed that the existing scrubber, with demisting equipment, would be retained. Proper demisting would remove entrained water droplets from the gas stream and thus prevent, or greatly reduce, the slagging that could result from dissolved solids in entrained water droplets. By designing the heating system to raise the gas stream in excess of 50°F above the wet bulb temperature, heat losses are allowed for. Additional ductwork and insulation have been included in the revised costs as recommended by Monsanto. Changes have also been made for the increased natural gas cost and altitude. Direct drive units were costed in the original estimates, rather than V-belt drives as believed by the commenter. As noted earlier, MRI has reevaluated the "Lang" cost factors for fabric filters. No justification can be found for raising the end value to 4 as suggested by Monsanto. The original values are believed to be adequate for this study.

In providing their comments, FMC was not aware that a fabric filter for their facility with a gas-fired reheater similar to that at Monsanto had also been costed. This approach would alleviate their concerns with regard to increased fluoride emissions. It is still believed that a fabric filter placed downstream of the fluoride scrubber provided with reheat capability, and utilizing an A/C ratio of 4:1 is a less-costly approach to solving the problem than that suggested by FMC. The air flows used in the analysis were based on those determined during the test program. The costs in Table 5.2 are those for the gas-fired reheater system.

5.5 REFERENCES

1. Sparks, L.E., Particle Collection Using a Venturi Scrubber. ACCESS. September/October 1982. pp. 24-29.

2. Calvert, S. Scrubbing. In: Air Pollution Volume 4. p. 281.

3. U.S. Environmental Protection Agency. Control Techniques for Particulate Emissions from Stationary Sources. Volume 1. Publication No. EPA-450/3-81-005a. September 1982. p. 4.5-21.

4. Wark, K., and C.F. Warner. Air Pollution: Its Origin and Control. IEP. New York. 1976. p. 216.

5. McIlvaine Scrubber Manual. Volume I, Chapter III. pp. 1.21-1.22.

6. McIlvaine Scrubber Manual. Volume III, Chapter XI. p. 8-6.

6.0 GENERAL

Comments 6.1: The specified review period was not sufficient to perform a review. A request was made for an extension of the docket period. (G-1, I-7)

Response: The Agency is committed by statute and policy to public participation in the decisionmaking process for its environmental regulations. This policy encourages and solicits communications and comments to the public docket. Contributions are desired from as many diverse views as possible. At times, extenuating circumstances cause EPA's docket periods to vary in length. In the present case, the U.S. District Court for the Northern District of California ordered EPA to take final action on its proposed standards by October 23, 1984. On August 24, 1984 (49 FR 33695), EPA opened Docket A-79-11, Section IV, until September 21, 1984, to allow for public comment on new information developed or received since our proposed rulemaking. This left the Agency with about 30 days for docket review, docket analysis, options evaluation, and preparation of final rulemaking documentation to comply with the court order. Accordingly, the Agency was not in a position to extend the docket period.

Comment 6.2: Persons have lived in naturally radioactive areas ("hot spots") without apparent harm. There is thus obviously doubt as to the productive value to the taxpayer of the proposed standards. (P-1)

Response: See Section 2.2 of Response to Comments Final Rules for Radionuclides, Volume I.

Comment 6.3: Risks associated with exposure to radon released during the operational phase of uranium mills compel immediate action by EPA. (P-2)

Response: EPA has issued an Advanced Notice of Proposed Rulemaking for uranium mills. The Agency has solicited information in a number of subject areas, including:

(1) radionuclide emissions from these facilities;

(2) applicable control options and strategies, including work practices;

(3) feasibility and cost of control options and strategies; and

(4) local and regional impacts due to emissions of radon-222 from active uranium mills.

These data will be used to develop work practice, design, equipment and/or operational standards to control radon releases from uranium mills.

Comment 6.4: Commenter believes that consideration of the potential increase from airborne radionuclide emissions from DOE facilities would strongly demonstrate the need for EPA regulation of such emissions. (P-6)

Response: It is the Administrator's judgment that the present record does not support a conclusion that regulation of DOE facilities for radionuclide emissions to air is necessary to protect the public health with an ample margin of safety, within the meaning of the Clean Air Act. The DOE currently has a program to keep exposure to the public to levels that are as low as reasonably achievable. This program is operated by the Department in keeping with the longstanding recommendations of the National Council on Radiation Protection and Measurements, the International Commission on Radiological Protection, and the Federal Radiation Council to avoid radiation exposure where practical. While the Agency recognizes that DOE facilities maintain very large quantities of radionuclides in their inventories at many of the facilities, there has been a general trend at most facilities for radionuclide emissions to be reduced over the years. See, also, the Federal Register Notice of Withdrawal.

Comment 6.5: It is inappropriate to establish standards below 500 mrems for known individuals and 170 mrems for members of the general public because these existing standards include a margin of safety. (I-2)

Response: Such levels of radiation exposure are generally recognized to represent a significant level of risk, especially if the exposure lasts for many years. Therefore, they are maximum permitted levels that should not be approached without good reasons, and people should not be exposed to such levels for any length of time. They do not represent an exposure level that provides, over a long term, an ample margin of safety for the public. Furthermore, they apply to the sum total of exposure to an individual from all pathways and all sources. They are not appropriate as limits for a single facility and a single pathway.

Comment 6.6: EPA's calculated cost of implementing the proposed standard is extraordinarily large in comparison with the health effects averted. (I-1)

Response: The Clean Air Act requires EPA to establish emission standards which, in the Administrator's judgment, provide an ample margin of safety to protect public health from hazardous air pollutants. In developing standards, EPA evaluates the availability, practicality, and cost of control technology to achieve reduced health effects. This consideration contributed to the Agency's decisions to withdraw the proposed standard for elemental phosphorus plants and not to regulate coal-fired boilers.

Comment 6.7: Notwithstanding the Science Advisory Board Committee's comments and recommendations, EPA's risk assessment is adequate to support the Agency's decision not to regulate emissions from coal-fired power plants. (I-9)

Response: EPA did not propose standards for coal-fired boilers for a number of reasons, including the assessment that the risks to nearby individuals and the total risk to populations due to radionuclides, as the result of particulate controls already in place, are not large.

Particulate emissions from new utility and new large industrial boilers are controlled by new source performance standards issued under Section III of the Clean Air Act, reflecting best demonstrated technology. EPA has also proposed new source performance standards for smaller industrial boilers. Existing utility and industrial boilers are regulated for particulate emissions by State implementation plans as required by the Clean Air Act.

EPA believes that it is unreasonable to issue a standard that duplicates current regulations. As a practical matter, the Clean Air Act regulations for particulates limit radionuclide emissions to low levels and protect the public health with an ample margin of safety (as far as radionuclide emissions are concerned).

After carefully considering all comments, EPA has affirmed its initial decision not to regulate radionuclide emissions from coal-fired boilers at this time.

Comment 6.8: EPA's dispersion modeling is suspect so long as the results have not been validated. (I-6)

Response: EPA attempts to model environmental transport of radioactivity as realistically as possible. As noted in the Science Advisory Board Subcommittee's report (p. 13), the level of uncertainty associated with dispersion models such as AIRDOS-EPA over flat terrain and for long-term averages ranges from a factor of about two for nearby receptors to a factor of four for more distant receptors.

Comment 6.9: A recent review of the lung cancer risk resulting from radon exposure to the general public concludes that:

a. Ionizing radiation is carcinogenic,
b. Radiation exposure is a significant cause of lung cancer,
c. Existing epidemiologic data may underestimate the risk of low dose exposures,
d. Low dose exposure may be more harmful in terms of unit dose than high dose exposure, and
e. The most appropriate method for determining health effects to the general public is the relative risk model.

Response: EPA agrees with the thrust of this comment. There is no scientific dispute that ionizing radiation is carcinogenic. EPA has estimated the risk of fatal lung cancer resulting from emissions of radionuclides. These estimates can be found in Volume II of the Background Information Document, EPA 520/1-84-022-2, October 1984.

Since 1978, EPA has based risk estimates of cancer resulting from inhaled radon-222 progeny on a linear dose response function, a relative risk projection model, and a minimum induction period of 10 years. Lifetime risks are projected on the assumption that exposure to 1 WLM increases the age-specific risk of lung cancer by 3 percent over the age-specific rate in the U.S. population as a whole.

In reviewing this model in terms of the more recent information, EPA has found that our major assumptions, linear response and relative risk projection, have been affirmed. The A-bomb survivor data clearly indicate that the absolute risk of radiogenic lung cancer has continued to increase among these survivors while their relative risk has remained reasonably constant. The UNSCEAR, ICRP, and 1980 NAS Committee have continued to use a linear dose response to estimate the risk of lung cancer resulting from inhaled radon progeny. Thomas and McNeill's analysis indicates that the use of linearity is not unduly conservative and may, in fact, underestimate the risk at low doses. The 1980 NAS BEIR Committee reached a similar conclusion.

The major weakness of the EPA model is the uncertainty in the relative risk coefficient used, a 3 percent increase per WLM. This value is based on the excess mortality resulting from lung cancer among exposed miners of various ages, many of whom smoked. Therefore, it is an average value for a mixed population of smokers and nonsmokers. Furthermore, the fact that smoking was more prevalent among some of the groups of miners studied than it is among the U.S. general population today may lead to a somewhat conservative risk estimate. In a recent paper, Radford and Remard reported on the results of a long-term study of Swedish iron workers who were exposed to radon progeny. This study is unique in that most of the miners were exposed to less than 100 WLM, and the risks to smokers and nonsmokers were considered separately. The absolute risk of the two groups was similar, 20 fatalities per 10^6 person WLM year for smokers compared to 16 for nonsmokers. The total number of lung cancer fatalities for nonsmokers is small, making the estimate of 16 not too reliable. Nonsmokers have a much lower baseline incidence of lung cancer mortality than smokers. This means that risk for the nonsmoking exposed miners relative to unexposed nonsmokers was about four times larger that the relative risk for exposed smokers. This large relative risk, however, does not compensate for the lower baseline incidence of nonsmokers. Therefore, the study of Swedish iron miners indicates that a 3 percent per WLM relative risk coefficient is conservative for the population as a whole. Further follow-up of this mining group may

provide more reliable data on the risk to nonsmokers, and we expect to incorporate separate consideration of smokers and nonsmokers into EPA analyses as more data become available.

A more detailed discussion of risk to low dose exposure appears in Chapter 8 "Estimating the Risk of Health Effects Resulting from Radionuclide Air Emission," EPA 5201/1-84-022-1, Volume I, October 1984.

EPA has considered the possibility that a linear dose-response model may underestimate the risk associated with low doses. See the response to Comment 13 in Section 2 of this volume.

APPENDIX A. GOVERNMENT COMMENTERS

I.D. Code	Docket Number	Commenter	Date of Submission	Date Docketed
G-1	IV-D-13	Martin E. Rivers Director of Environmental Quality Tennessee Valley Authority Knoxville, Tennessee 37902	9-20-84	9-25-84

APPENDIX B. INDUSTRY COMMENTERS

I.D. Code	Docket Number	Commenter	Date of Submission	Date Docketed
I-1	IV-D-2	Don G. Scroggins Beveridge and Diamond, P.C. 1333 New Hampshire Ave. N.W. Washington, D.C. 20036	9-10-84	9-19-84
I-2	IV-D-4	J. Allen Overton, Jr. American Mining Congress 1920 N. Street N.W. Washington, D.C. 20036	9-21-84	9-21-84
I-3	IV-D-6	Gary D. Myers The Fertilizer Institute 1015 18th Street N.W. Washington, D.C. 20036	9-21-84	9-21-84
I-4	IV-D-8	G.C. Sorensen Washington Public Power Supply System P.O. Box 968 3000 George Washington Way Richland, Washington 99352	9-20-84	9-20-84
I-5	IV-D-11	Robert G. Beverly Umetco Minerals Corporation P.O. Box 1029 Grand Junction, Colorado 81502	9-19-84	9-24-84
I-6	IV-D-12	J.C. Stauter Kerr-McGee Corporation Kerr-McGee Center Oklahoma City, Oklahoma 73125	9-21-84	9-24-84
I-7	IV-D-14	Gary H. Baise Beverly and Diamond, P.C. 1333 New Hampshire Ave., N.W Washington, D.C. 20036 (Counsel, The Idaho Mining Association)	9-21-84	9-26-84
I-8	IV-D-15	Middle South Services, Inc. P.O. Box 61000 New Orleans, LA 70161	9-20-84	9-26-84

APPENDIX B. INDUSTRY COMMENTERS (cont')

I.D. Code	Docket Number	Commenter	Date of Submission	Date Docketed
I-9	IV-D-16	Henry V. Nickel, et al. Hunton and William 2000 Pennsylvania Ave., N.W. P.O. Box 19230 Washington, D.C. 20036 (Counsel, Utility Air Regulatory Group)	9-21-84	10-01-84
I-10	IV-D-17	J.P. Hyland Monsanto Industrial Chemical Co. 800 N. Lindbergh Blvd. St. Louis, Missouri 63167	9-21-84	10-05-84
I-11	IV-D-18	The Idaho Mining Association Statehouse Square 802 Banock, Suite 301 Boise, Idaho 83701	9-21-84	10-11-84
I-12	IV-D-19	FMC Corporation 200 Market Street Philadelphia, PA 19103	9-21-84	10-11-84

APPENDIX C. PUBLIC COMMENTS

I.D. Code	Docket Number	Commenter	Date of Submission	Date Docketed
P-1	IV-D-1	C.G. Bacon 2960 Hannah Ave. Norristown, PA 19401	No date	9-05-84
P-2	IV-D-3	Dr. Ellen Silbergold, et al. Environmental Defense Fund 1405 Arapahoe Avenue Boulder, Colorado 80302	9-21-84	9-21-84
P-3	IV-D-5	Leonard D. Hamilton Brookhaven National Laboratory Upton, Long Island, New York 11973	9-20-84	9-21-84
P-4	IV-D-9	James B. Morton Environmental Defense Fund 1405 Arapahoe Avenue Boulder, Colorado 80302	9-20-84	9-20-84
P-5	IV-D-10	Gloria C. Rains Manasota 88 5314 Bay State Road Palmetto, Florida 33561	9-17-84	9-21-84
P-6	IV-D-7	Barbara A. Finamore Suite 300 Natural Resources Defense Council, Inc. 1350 New York Avenue N.W. Washington, D.C. 20005	9-21-84	9-12-84